

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF TEXAS
HOUSTON DIVISION**

NIPUN KAKKAR, Individually and on
Behalf of All Others Similarly Situated,

Plaintiff,

vs.

BELLICUM PHARMACEUTICALS, INC.,
THOMAS J. FARRELL, RICHARD A. FAIR,
ALAN A. MUSSO, AND ANNEMARIE
MOSELEY

Defendants.

Case No. 4:18-cv-00338

JURY TRIAL DEMANDED

AMENDED CLASS ACTION COMPLAINT

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Lead Plaintiff Bellicum Investor Group (“Plaintiff”), individually and on behalf of all other persons similarly situated, by its undersigned attorneys, for its complaint against Defendants, alleges the following based upon personal knowledge as to itself and its own acts, and information and belief as to all other matters, based upon, *inter alia*, the investigation conducted by and through its attorneys, which included, among other things, a review of the Defendants’ public documents, conference calls and announcements made by Defendants, United States Securities and Exchange Commission (“SEC”) filings, wire and press releases published by and regarding Bellicum Pharmaceuticals, Inc. (“Bellicum” or the “Company”), analysts’ reports and advisories about the Company, and information readily obtainable on the Internet. Plaintiff believes that substantial evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

I. NATURE OF THE ACTION

1. This is a federal securities class action on behalf of a class consisting of all persons other than Defendants who purchased or otherwise acquired Bellicum’s securities between January 13, 2015 and January 30, 2018, both dates inclusive (the “Class Period”), seeking to recover damages caused by Defendants’ violations of the federal securities laws and to pursue remedies under Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 (the “Exchange Act”) and Rule 10b-5 promulgated thereunder, against the Company and certain of its top officials.

2. Bellicum operates as a clinical stage biopharmaceutical company. The Company focuses on discovering and developing novel cellular immunotherapies for various forms of cancer and other diseases. Per Bellicum’s SEC filings, the Company is “not profitable, ha[s] no products approved for commercial sale and ha[s] incurred significant losses since our inception

in 2004.” With no approved products generating revenue, Bellicum has only been able to finance its operations by relying primarily on equity and debt financings.

3. The Company’s lead clinical product candidate, BPX-501, now known as rivogenlecleucel or Rivo-cel, is described as an adjunct T-cell therapy administered after allogeneic hematopoietic stem cell transplantation (“HSCT”). Allogenic HSCT is a procedure used to treat blood-related cancers. It involves the transferring of healthy blood-forming stem cells from a healthy genetically similar donor to the patient. When a transplant is successful, the donor stem cells can replace stem cells in the bone marrow, potentially providing the only long-term cure of the patient’s disease. The donated cells produce white blood cells that attack any remaining cancer cells in the patient’s body.

4. However, allogenic HSCT can result in serious complications. BPX-501 is purportedly designed to improve the chances of transplant success, accelerate the recovery of the depleted immune system, and decrease infection and relapse rates, and to do so better than any alternative in the same pharmaceutical space.

5. Bellicum began Phase 1/2 clinical trials of BPX-501 in 2014. However, the procedures and protocols it had in place to monitor and report adverse events suffered egregious deficiencies. These deficiencies had particular relevance because, during the Phase 1/2 clinical trial, referred to as BP-004, which took place in both European and U.S. transplant centers, three patients treated with the drug suffered from encephalopathy, which generally refers to brain disease, damage, or malfunction. One of those patients died. Nevertheless, through the Class Period, while touting the BPX-501 clinical trial program and safety results, Defendants never divulged the foregoing troubling facts.

6. Indeed, Defendants made materially false and misleading statements throughout the Class Period regarding the Company's clinical program for BPX-501, and risks associated with the drug. Specifically, Defendants made false and/or misleading statements and/or failed to disclose that: (i) a substantial risk of encephalopathy was associated with the Company's lead product candidate BPX-501 and multiple encephalopathy adverse events occurred; (ii) the Company's clinical trial procedures and protocols had a deficiency in their monitoring and management of such neurological adverse events; and (iii) FDA approval was less likely and/or clinical trial delay was more likely than represented.

7. On January 30, 2018, the Company belatedly revealed post-market that three cases of encephalopathy had occurred during the pediatric BPX-501 clinical trials, at three different treatment centers, which were deemed plausibly related to BPX-501. One of the patients died.

8. That day, Bellicum issued a press release entitled "Bellicum Pharmaceuticals Announces Clinical Hold on BPX-501 Clinical Trials in the United States," announcing that it had "received notice from the U.S. Food and Drug Administration (FDA) that U.S. studies of BPX-501 have been placed on a clinical hold following three cases of encephalopathy deemed as possibly related to BPX-501." The hold, which placed an indefinite freeze on Bellicum's efforts to clinically test BPX-501, meant not only a delay in the Company's ability to seek FDA approval but potentially an insurmountable obstacle to approval altogether.

9. Shocked by news of the FDA hold, Bellicum's share price fell \$2.12, or 25.85%, to close at \$6.08 on January 31, 2018.

10. As Bellicum explained in its March 2018 10-Q, the Company could not conduct any clinical trials on BPX-501 until the clinical hold is lifted by the FDA. The FDA hold also

raised the risk that foreign regulatory authorities would similarly impose clinical holds on ongoing trials of BPX-501, “which would significantly delay our development and could end our development of BPX-501.”

11. According to Bellicum, the FDA issued the hold not only because of these adverse events but also due to its concerns with Bellicum’s underlying clinical procedures and protocols in testing BPX-501, with particular focus on the Company’s monitoring and management of such adverse events.

12. As a result of Defendants’ wrongful acts and omissions, and the precipitous decline in the market value of the Company’s securities, Plaintiff and other Class members have suffered significant losses and damages.

II. JURISDICTION AND VENUE

13. The claims asserted herein arise under and pursuant to Sections 11 and 15 of the Securities Act (15 U.S.C. §§ 77k and 77o), and Sections 10(b) and 20(a) of the Exchange Act (15 U.S.C. §§ 78j(b) and 78t(a)) and Rule 10b-5 promulgated thereunder by the SEC (17 C.F.R. § 240.10b-5).

14. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §1331, Section 22 of the Securities Act (15 U.S.C. § 77v), and Section 27 of the Exchange Act (15 U.S.C. §78aa).

15. Venue is proper in this Judicial District pursuant to §27 of the Exchange Act (15 U.S.C. §78aa) and 28 U.S.C. §1391(b) as substantial acts in furtherance of the alleged fraud or the effects of the fraud have occurred in this Judicial District. Bellicum’s principal executive offices are located within this District.

16. In connection with the acts, conduct and other wrongs alleged in this Complaint, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce,

including but not limited to, the United States mail, interstate telephone communications and the facilities of the national securities exchange.

III. PARTIES

17. Plaintiff, as set forth in the previously filed Certification, acquired Bellicum securities at artificially inflated prices during the Class Period and was damaged upon the revelation of the alleged corrective disclosures.

18. Defendant Bellicum is headquartered in Texas, with its principal executive offices located at 2130 West Holcombe Boulevard, Suite 800, Houston, Texas 77030. Bellicum's shares trade on the NASDAQ under the ticker symbol "BLCM."

19. Defendant Thomas J. Farrell ("Farrell") was the Company's Chief Executive Officer ("CEO") and President from February 2006 until January 2017, and a Director from April 2007 until January 2017. He became an advisor for the Company in January 2017.

20. Defendant Richard A. Fair ("Fair") has served as the Company's Chief Executive Officer, President, and Director since January 2017.

21. Defendant Alan A. Musso ("Musso") had served as the Company's Chief Financial Officer ("CFO") and Treasurer starting in November 2014, prior to his departure from Bellicum in September 2018.

22. Defendant Annemarie Moseley ("Moseley") was Chief Operating Officer ("COO") and Executive Vice President of Clinical Development at the Company from November 2012 until July 2017. In July 2017, she resigned from those positions and was made a consultant until departing in January 2019.

23. The Defendants referenced above in ¶¶ 19-22 are sometimes referred to herein as the "Individual Defendants."

24. The Individual Defendants possessed the power and authority to control the contents of Bellicum's SEC filings, press releases, and other market communications. The Individual Defendants were provided with copies of the Company's SEC filings and press releases alleged herein to be misleading prior to or shortly after their issuance and had the ability and opportunity to prevent their issuance or to cause them to be corrected. Because of their positions with the Company, and their access to material information available to them but not to the public, the Individual Defendants knew that the adverse facts specified herein had not been disclosed to and were being concealed from the public, and that the positive representations being made were then materially false and misleading. The Individual Defendants are liable for the false statements and omissions pleaded herein.

IV. SUBSTANTIVE ALLEGATIONS

25. Bellicum is self-described as "a clinical stage biopharmaceutical company with a limited operating history" which is "not profitable, ha[s] no products approved for commercial sale and ha[s] incurred significant losses since our inception in 2004." Its lead drug candidate, BPX-501, is a T-cell therapy used during transplants of stem cells from bone marrow and blood. These transplants are used to treat hematological (blood-related) cancers such as leukemias and lymphomas, and also non-cancerous inherited blood disorders. The stated role of BPX-501 is to improve the chances of transplant success, accelerate the recovery of the depleted immune system, and decrease infection and relapse rates, and to do so better than any alternative in the same pharmaceutical space.

26. As with any new drug, in order to obtain approval to market and sell BPX-501 in the United States, Bellicum has to follow FDA rules and regulations regarding clinical testing to prove the drug's safety and efficacy. This includes human clinical trials that proceed in three phases:

- Phase 1 clinical trials are conducted in a small number of volunteers or patients to assess the early tolerability and safety profile, and the pattern of drug absorption, distribution and metabolism;
- Phase 2 clinical trials are conducted in a limited patient population afflicted with a specific disease in order to assess appropriate dosages and dose regimens, expand evidence of the safety profile, and evaluate preliminary efficacy;
- Phase 3 larger scale, multicenter, well-controlled clinical trials are conducted on patients with a specific disease to generate enough data to statistically evaluate the efficacy and safety of the product for approval, as required by the FDA, to establish the overall benefit-risk relationship of the drug and to provide adequate information for the labeling of the drug.

27. According to FDA regulations, the FDA must be notified no later than 15 days after learning of a “serious adverse drug experience,” which includes any reaction that is fatal, life threatening, or requires in-patient hospitalization or prolongs hospitalization. If it is an “unexpected” reaction, the FDA must be notified by telephone, facsimile transmission, or in writing, within 7 calendar days of the receipt of that information. A complete written report must follow within 8 calendar days. The FDA considers all of the clinical trials results and nonclinical studies in determining whether to approve a drug for market. *See* 21 C.F.R. §§ 314.125(b), 314.126(a).

28. In 2014, Bellicum initiated BP-004¹, a Phase 1/2 clinical trial conducted in both European and U.S. pediatric transplant centers, in children with leukemia, lymphoma, or orphan

¹ The BP-004 EU Study: *Safety Study of Gene Modified Donor T-cells Following TCR Alpha Beta Depleted Stem Cell Transplant*, ClinicalTrials.Gov (available at <https://clinicaltrials.gov/ct2/show/NCT02065869>, last accessed Apr 25, 2019).

inherited blood disorders, such as severe combined immunodeficiency, Wiskott-Aldrich Syndrome and beta thalassemia, all fatal or chronic life-long disorders for which HSCT is curative.

29. Unbeknownst to investors, the BPX-501 clinical trial protocols suffered severe deficiencies concerning the monitoring and managing of neurotoxicity and all related adverse events that raised a strong risk that the FDA would force Bellicum to cease conducting any BPX-501 studies until the deficiencies were resolved.

30. While conducting the clinical trials with these deficient procedures in place, three pediatric patients treated with BPX-501 in the BP-004 trial suffered a severe adverse event known as encephalopathy. Encephalopathy is a general term referring to brain disease, damage, or malfunction. Each case of encephalopathy occurred in a different treatment center. One of the patients died as a result.

31. Bellicum had a safety database for the clinical trials. ***Adverse events were entered into the database within 24 hours of occurrence.*** Bellicum is required to notify the FDA of adverse events within 15 days.

32. At no point during the Class Period did Defendants divulge to investors that their prime candidate for FDA approval, and only chance for revenue generation to staunch Bellicum's dwindling cash supply in the near future, suffered this staggering blow during clinical testing aimed at proving the *safety of the drug for commercial use*.

33. In 2017, after the adverse encephalopathy events had occurred, Bellicum hired Dr. Paul Woodard ("Woodard") as the VP of clinical development responsible for managing the clinical trials with clinical trial design, strategy, and medical oversight. The choice to hire

The BP-U-004 U.S. Study: *Study of Gene Modified Donor T-cells Following TCR Alpha Beta Positive Depleted Stem Cell Transplant*, ClinicalTrials.gov (available at <https://clinicaltrials.gov/ct2/show/NCT03301168>, last accessed Apr 25, 2019).

Woodard at this time is telling. Over a decade prior, in 2004, Woodard co-authored a scientific paper discussing HSCT, the procedure for which BPX-501 is designed, wherein he describes the encephalopathy risks associated with HSCT and the grave danger to the patient when it occurs.²

34. Also, in mid-2017, Defendant Moseley resigned as COO and Executive Vice President of Clinical Development after having a leading role in clinical development, including co-authoring numerous scientific posters and reports used prominently in Bellicum presentations.

35. Then, after hiring Woodard, but well prior to shocking the market with news of the cases of encephalopathy and deficiencies in the BPX-501 clinical trial procedures for monitoring and managing adverse events, Bellicum informed European regulators about the three encephalopathy adverse events.

36. Unsurprisingly given the significance of BPX-501 to Bellicum, Confidential Witnesses confirm that the cases of encephalopathy were well known and discussed throughout the Company. Confidential Witness (“CW”) 1 worked at Bellicum’s Houston headquarters from early 2016 until July 2017. CW1 purchased materials used to manufacture the drugs tested in clinical trials and worked closely with the manufacturing department. CW1 reported to Alan K. Smith, then the Senior Vice President of Manufacturing, and Kurt Mickelson, the Clinical Supply Chain Director.

37. CW1 knew about the patient death due to encephalopathy in the U.K. BP-004 BPX-501 trial from a colleague in the manufacturing department. According to CW1, both Smith and Mickelson knew about the death as well. Smith reported directly to CEO Fair. CW1

² This study focused on encephalopathy complications arising from HSCT in children, noting that the literature has some papers on adults, but none for children. Thus, it was a seminal work for studying neurotoxicity arising from pediatric HSCT, making Woodard highly qualified on this topic. See Paul Woodard et al., *Encephalopathy in pediatric patients after allogeneic hematopoietic stem cell transplantation is associated with a poor prognosis*, 33 Bone Marrow Transplantation 1151–1157 (2004). According to his search results on Google Scholar, Dr. Paul Woodard has written numerous papers about HSCT and the adverse events that can arise during the procedure, with two of those papers focusing specifically on neurological toxicity adverse events.

stated that the death was common knowledge, and openly discussed throughout the Company, though never disclosed publicly during the Class Period.

38. CW1 also noticed that Bellicum massively slowed down production of BPX-501 in mid-2017 and, after inquiring, was told that the encephalopathy death likely influenced the slowdown.

39. CW2 also worked at Bellicum from January 2017 until May 2018 conducting medical reviews, assessments, and interpretations of clinical and safety data, to ensure reports were accurate and up to par with industry standards. CW2 reported to Paul Woodard, VP of clinical development.

40. CW2 knew about all three cases of encephalopathy, including the death, and stated that they were common knowledge. Indeed, CW2 confirmed that after each case of encephalopathy occurred, the Company filed a “Serious and Unexpected Event Report” with the FDA within 15 days.

41. In other words, Bellicum and the Individual Defendants had to have known about any adverse events, including the cases of encephalopathy promptly after occurrence.

42. Despite knowing these roadblocks existed on the path to approval, Defendants issued false and misleading statements, and omissions, throughout the Class Period touting the progress of the clinical program and safety results, leading investors to incorrectly believe that BPX-501 was heading towards FDA approval unobstructed by protocol flaws, and unimpeded by safety risks and adverse events.

V. MATERIALLY FALSE AND MISLEADING STATEMENTS AND OMISSIONS

43. The Class Period begins on January 13, 2015, when Bellicum issued a press release entitled, “Bellicum Pharmaceuticals Announces Successful Dosing of First Patient

Cohort With BPX-501 T Cells Following Haplo-Identical Hematopoietic Stem Cell Transplant,” which contained a quote from CEO Farrell stating:

We’re pleased to have successfully launched a **clinical program acceptable to U.S. and European regulatory agencies** that allows us to include patients with blood cancers and up to 18 different non-malignant blood diseases under a single protocol. We believe BPX-501 may have the potential to make alternative donor haplo-identical stem cell transplants as routine as conventional transplants from matched donors, enabling a treatment known to be curative, and making it available for many more patients suffering from a wide range of deadly and life-long diseases.

(Emphasis added.)

44. This statement was false and misleading because it states that the clinical program is acceptable to the U.S. regulatory agency (the FDA), but failed to disclose the severe flaws within the BPX-501 program, namely the sub-standard protocol for monitoring and management of adverse events, that ultimately led the FDA to place a hold on the BPX-501 clinical trials. Defendants also failed to disclose that the *unacceptable* BPX-501 clinical program, which led to three cases of encephalopathy, raised a serious risk to the timing and ultimate approvability of Bellicum’s lead drug candidate, and with no approved products generating revenue, to the Company’s overall financial viability.

45. Despite the egregious flaws in the BPX-501 clinical program, Defendants consistently painted a rosy picture of a smooth approval process for investors. On March 11th, 2015, Bellicum held an earnings call to discuss their results for the Fourth Quarter of 2014 and 2014 annually. In that call with analysts, Farrell stated:

So as we look to the remainder of 2015, pursuant to our strategy to pursue global regulatory approval and expand the potential addressable patient population for BPX-501, we intend to initiate additional Phase 1/2 clinical trials in different transplant settings in both the United States and Europe.

46. On March 20, 2015, Bellicum filed its 2014 Annual Report on Form 10-K, containing its financial and operating results for the quarter and year ended December 31, 2014 (the “2014 10-K”), with signed certifications pursuant to the Sarbanes-Oxley Act of 2002 (“SOX”) by Defendants Farrell and Musso, stating that the 2014 10-K “does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report.”

47. In the 2014 10-K, the Company stated:

We are currently conducting three Phase 1/2 clinical trials of BPX-501 at leading transplant centers in the United States and Europe: BP-001, a clinical trial in adults in which BPX-501 is administered after initial allogeneic HSCT for hematological cancers, BP-003, a clinical trial in children with orphan inherited blood disorders in which BPX-501 is administered after initial allogeneic HSCT, and BP-004 an additional Phase 1/2 clinical trial in children with hematological cancers or orphan inherited blood disorders. In addition, we are planning to initiate additional Phase 1/2 clinical trials in the United States and Europe in 2015, as part of our strategy to pursue a global regulatory approval and expand the potential addressable patient population for BPX-501.

48. The 2014 10-K further stated:

In all cases, the clinical trials are conducted in accordance with **GCP** and the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki.

* * *

[W]e are responsible for ensuring that each of our studies is conducted in accordance with applicable protocol, legal, regulatory and scientific standards, and our reliance on third parties does not relieve us of our regulatory responsibilities. We and these third parties are required to **comply with current good clinical practices, or cGCPs, which are regulations and guidelines enforced by the FDA** and comparable foreign regulatory authorities for product candidates in clinical development.

(Emphasis added.)

49. The foregoing statements in ¶¶ 45-48 were false and misleading because in opting to speak about Bellicum’s pursuit of regulatory approval for BPX-501 by means of clinical trials

and representing the trials as following good clinical practices, Defendants failed to explain that its clinical program suffered severe flaws in monitoring and managing adverse events that could ultimately lead the FDA to either delay or altogether prevent completion of clinical testing or the approval of the drug.

50. On August 13, 2015, Bellicum filed a Form 8-K with the SEC, signed by Defendant Musso, along with an Operational Update and Financial Report for the Second Quarter ended June 30, 2015, attached as an exhibit. In it, CEO Tom Farrell states:

In our lead BPX-501 clinical program, we have been pleased with the strong pace of patient recruitment into our **BP-004 study**. This study is evaluating pediatric patients with orphan genetic diseases or hematological cancers who undergo a haploidentical allogeneic hematopoietic stem cell transplant to attain a disease cure. We are assessing safety and the recovery of the immune system, and remain on track to present initial top-line results from approximately 40 patients in December of this year. BPX-501 is designed to address the clear medical need for a **safer**, more effective transplant option for patients who do not have a matched donor.

(Emphasis added.)

51. On August 13, 2015, in Bellicum's Second Quarter 2015 Earnings call, Defendant Moseley said:

I'd like to take a step back and talk about the goals of our **BPX-501 program** and what we're looking for in terms of **safety** and efficacy.

* * *

To address these issues in the haplo setting, we've developed BPX-501, an adjunct cellular therapy of genetically modified T cells which incorporate our proprietary clinically validated CaspaCIDE safety switch. The product is **designed to provide a safety net** so that physicians can perform haplo stem cell transplants, and add back the important T cells to speed immune reconstitution and control infections.

(Emphasis added.)

52. In the same Second Quarter 2015 Earnings call, Musso stated:

[W]e believe BPX-501 could make a therapy known to be curative, safer, more effective and available for many more patients with a wide range of lifelong and deadly diseases.

53. The foregoing statements in ¶¶ 50-52 were false and misleading because in opting to speak about (i) Bellicum's pursuit of regulatory approval for BPX-501 by means of clinical trials, (ii) the safety of the drug, or (iii) representing the trials as following good clinical practices, Defendants failed to explain that its clinical program suffered severe flaws in monitoring and managing adverse events that could ultimately lead the FDA to either delay or altogether prevent completion of clinical testing or the approval of the drug .

54. On December 5, 2015, Bellicum presented at the 57th American Society of Hematology Annual Meeting, with Moseley as co-author of the presented abstract, which stated, in relevant part:

Conclusions: Overall, these data indicate that the infusion of BPX-501 cells is **safe** and well tolerated. The 100-day CI of skin-only grade I-II acute GvHD observed in these patients is similar to that of children included in the previous trial of haplo-HSCT after depletion of α/β T cells. BPX-501 cells expand in vivo and persist over time, potentially contributing to accelerate the recovery of adaptive T-cell immunity, with improved clinical outcome. The iC9 cell-suicide system may increase the implementation of cellular therapy approaches aimed at optimizing immune recovery after transplantation.

(Emphasis added.)

55. The foregoing statements were false and misleading for the reasons set forth in ¶ 53.

56. On March 14, 2016, Bellicum filed its 2015 Annual Report on Form 10-K, containing its financial and operating results for the quarter and year ended December 31, 2015 (the "2015 10-K"), with signed certifications pursuant to SOX, like those described in ¶ 46, by Defendants Farrell and Musso. The 2015 10-K repeated the misstatements contained in the 2014 10-K.

57. Also, on March 14, 2016, Bellicum held its Fourth Quarter 2015 Earnings call, in which Moseley stated: “BPX-501 with its CaspaCIDE safety net addresses physician’s reluctance to perform these potentially risky haplo-transplants.” In that same call, Farrell said, in relevant part:

We believe our cell therapies have disruptive potential with the **unique safety** and efficacy benefits. As you know, we recently met with the National Institutes of Health Recombinant DNA Advisory Committee which reviewed product candidates involving gene transfer about the BPX-501 and BPX-601 protocols. We believe the meetings went well and are moving forward with our plan to file IND with the FDA for these product candidates.

(Emphasis added.)

58. Defendant Farrell went on to say:

We look forward to meeting with regulators in Europe and the US in the second quarter with the goal of defining the path to regulatory filing and approval initially in non-malignant pediatric genetic diseases.

59. The foregoing statements in ¶¶ 56-58 were false and misleading for the reasons set forth in ¶ 53.

60. On April 5, 2016, in a press release titled “Bellicum Pharmaceuticals Announces BPX-501 Clinical Data Updates,” Farrell said:

In both malignant and nonmalignant patients, the results show **that treatment with BPX-501 appears safe, well-tolerated**, and provides important immune benefits,” commented Tom Farrell, President and CEO of Bellicum Pharmaceuticals. “These data also demonstrate high BPX-501 cell viability, expansion and persistence, and that the improvement of immune reconstitution is sustained. We look forward to sharing more results as these data mature, and providing updates following our plan to meet with the U.S. FDA and EMA during the second quarter of this year.

(Emphasis added.)

61. The foregoing statements were false and misleading for the reasons set forth in ¶ 53.

62. On May 9, 2016, Bellicum filed a Form 8-K with the SEC, signed by Defendant Musso, along with an Operational Update and Financial Report for the First Quarter Ended March 31, 2016, attached as an exhibit. The filing had the following statement:

Preparing to meet with the European Medicines Agency and **U.S. FDA**, with the goal of defining the path to regulatory filing and approval.

(Emphasis added.)

63. The foregoing statement was false and misleading for the reasons set forth in ¶ 53.

64. On June 11, 2016, the Company presented at the 21st Congress of the European Hematology Association, with Defendant Moseley again as a co-author of a presented abstract, which contained, in relevant part, the following statement:

Conclusion

These data indicate that the infusion of BPX-501 cells in children with acute leukemia given selectively manipulated haploHSCT results in the absence of transplantation-related mortality...

65. The foregoing statements were false and misleading for the reasons set forth in ¶ 53.

66. On August 8, 2016, Bellicum again held an earnings call, this time for discussion of their Second Quarter results for 2016, with CEO Farrell saying:

We are pleased with the progress we have made toward defining an **expedient pathway** to the potential approval of BPX-501 and rimiducid for pediatric transplant patients in Europe. We're now initiating discussions with the FDA and expect to be able to provide additional guidance on the approval pathways in both markets during the fourth quarter.

(Emphasis added.)

67. Later on the call, an analyst asked Farrell about the issues faced by peers in the T-Cell space and whether Bellicum faced extra scrutiny for BPX-501. This question likely refers to

pharmaceutical competitor Juno's similar issues with neurotoxicity revealed shortly prior to this call. Farrell said:

No. Our most recent interactions have been around BPX-601 and 701. I think our observation would be that they are being careful in their review, they appear to be applying some sort of consistent thinking, two novel constructs coming through their office, but I don't think we've seen anything that we could say was explicitly tied to specific recent circumstances.

68. The foregoing statements in ¶¶ 66-67 were false and misleading for the reasons set forth in ¶ 53.

69. On November 9, 2016, Bellicum filed a Quarterly Report on form 10-Q with the SEC, announcing financial and operating results for the quarter ended September 30, 2016 (the "Q3 2016 10-Q"). The Q3 2016 10-Q contained signed certifications pursuant to SOX, like those described in ¶ 46, by Defendants Farrell and Musso.

70. In the Q3 2016 10-Q, the Company stated, in relevant part:

Discussions are ongoing with European Medicines Agency (EMA) and the FDA in regards to approval requirements for BPX-501 and rimiducid. Details regarding specific study endpoints and the data analysis plan are being refined in a formal protocol assistance process with EMA. The Company has also initiated dialogue with the FDA to define a U.S. regulatory pathway. We expect to have guidance from EMA by year end, and anticipate that the FDA regulatory interactions will continue into 2017.

71. The foregoing statements in ¶¶ 69-70 were false and misleading for the reasons set forth in ¶ 53.

72. In an abstract of a presentation given by Bellicum December 3, 2016, at the 58th American Society of Hematology Annual Meeting, in which Moseley was a co-author, and Bellicum Vice President of Regulatory Affairs Martha French was as well, it was stated:

Conclusions: Children with hemoglobinopathies and DBA can benefit from curative haplo-HSCT after depletion of α/β T-cells followed by infusion of BPX-501 cells, which, expanding and persisting over time, contribute to speed immune recovery of adaptive T-cell immunity, thus rendering the procedure **safer**.

(Emphasis added).

73. The foregoing statements were false and misleading for the reasons set forth in ¶ 53.

74. On December 5, 2016, Bellicum released a press release titled “Bellicum Presents Clinical Results to Date of BPX-501 Pediatric Program and Provides Regulatory Update at Investor Event During ASH Annual Meeting,” in which the Company states that it “continues to discuss the regulatory path to approval in the U.S. with FDA...”

75. The foregoing statement was false and misleading for the reasons set forth in ¶ 53.

76. On March 13, 2017, Bellicum filed its 2016 Annual Report on Form 10-K, containing its financial and operating results for the quarter and year ended December 31, 2016 (the “2016 10-K”), with signed certifications pursuant to SOX, like those described in ¶ 46, by Defendants Farrell and Musso. In the 2016 10-K the Company repeated representations that it conducts the BPX-501 clinical trials in accordance with good clinical practices enforced by the FDA.

77. The 2016 10-K also contains the following statements from the Company:

We have discussions ongoing with the FDA regarding the regulatory path to approval in the U.S. and we expect to provide updates in the first half of 2017.

* * *

In addition, we are planning to initiate additional Phase 1/2 clinical trials in the U.S. and Europe, as part of our strategy to pursue global regulatory approvals and expand the potential addressable patient population for BPX-501.

78. On March 13, 2017, Bellicum filed a Form 8-K (the “March 13, 2017 8-K”) with the SEC, signed by Defendant Musso, along with an Operational Update and Financial Report for 2016 Annually and the Fourth Quarter ended December 31, 2016, attached as an exhibit. In

it, CEO Richard Fair mentions Bellicum's progress on *registration trials (last phase trials)* and says:

On the regulatory front, we clarified our path to approval with BPX-501 and rimiducid in Europe, and made substantial progress in dialogue with the FDA on the design of U.S. registration trials.

79. The March 13 8-K also has the following company statement:

The Company advanced discussions with the U.S. FDA on BPX-501's path for product registration in the U.S.

(Emphasis in original.)

80. The foregoing statements in ¶¶ 76-79 were false and misleading for the reasons set forth in ¶ 53.

81. On March 13, 2017, Bellicum also had an earnings call with analysts for their Fourth Quarter 2016 results. The Call contained these statements from Fair:

[O]ur team and our collaborators have made significant clinical and regulatory progress over the past year on BPX-501.

* * *

In the U.S., we're pleased to report that we've made substantial progress in our ongoing discussions with the FDA on the design of U.S. registration trials. We expect to conduct two separate trials in pediatric patients receiving haplo-transplants, including a non-randomized trial in patients with orphan inherited blood disorders and a controlled study in patients with blood cancers. We expect to finalize discussions with the FDA on both protocols in the second quarter of this year and begin enrollment for these trials during the second half.

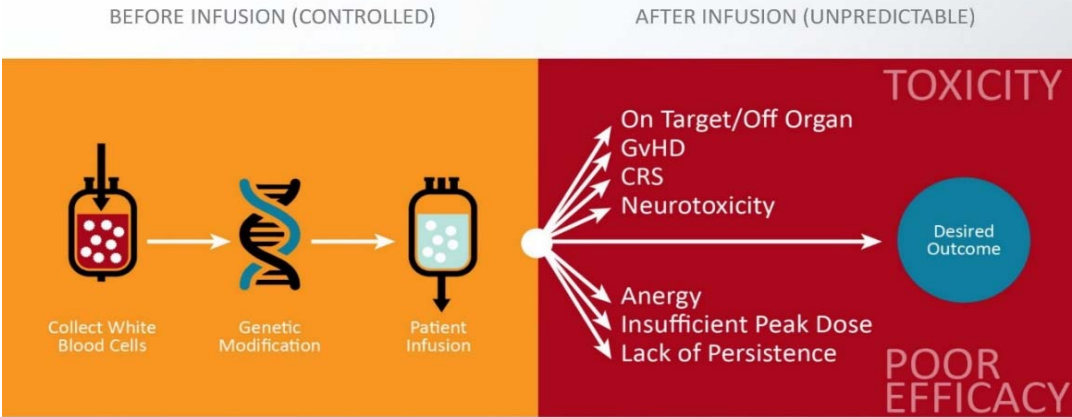
82. The foregoing statements were false and misleading for the reasons set forth in ¶ 53.

83. On March 15, 2017, Bellicum presented at the 2017 Barclays Global Healthcare Conference. The following two slides were featured:

Overview

Most cell therapies can only control steps BEFORE infusion

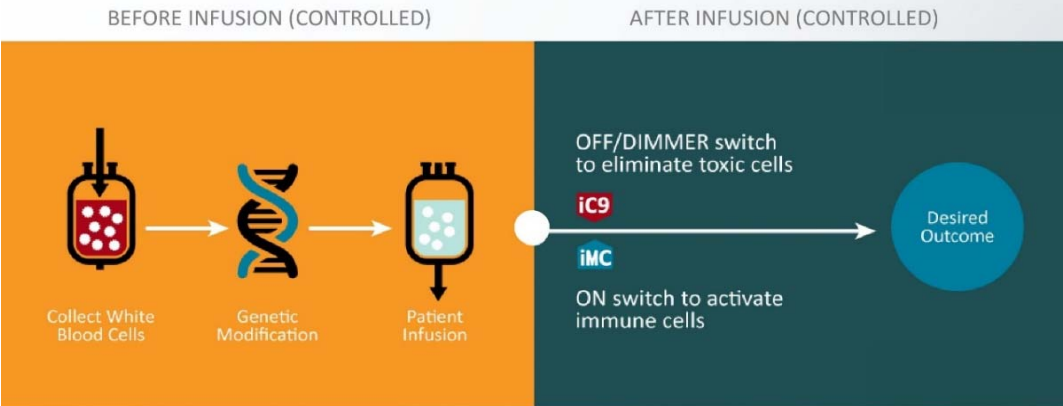
PAGE
3



Overview

Bellicum's molecular switches allow control AFTER infusion

PAGE
4



84. These two slides, taken together, make the claim that other cell therapies lead to toxicity, such as neurotoxicity, but that BPX-501 eliminates these ill effects. The foregoing statements in the slides were false and misleading for the reasons set forth in ¶ 53.

85. On May 8, 2017, Bellicum filed a Form 8-K with the SEC (the “May 8, 2017 8-K”), signed by Defendant Musso, along with an Operational Update and Financial Report for the First Quarter ended March 31, 2017, attached as an exhibit. In it, Fair states: “We continued to make progress on the registration trial for BPX-501, and presented updated clinical data highlighting its potential to transform patients’ lives.” The form also contained this statement from the Company:

• Preparation Ongoing for U.S. Registration Trials

Bellicum continues to prepare for pivotal trials of BPX-501 in the U.S. in pediatric patients with orphan inherited blood disorders and blood cancers and in adults with high- and intermediate-risk AML receiving haploidentical transplant.

86. The May 8 8-K also contained this statement:

• Data Update Highlights Promise of BPX-501 Clinical Program

At the Bone Marrow Transplant (BMT) Tandem Meeting in February, Bellicum reported data from the BP-004 trial which showed a low incidence of transplant-related mortality, rapid immune recovery, a low rate of GvHD that was manageable with standard treatments or rimiducid, and **no serious adverse events associated with the use of BPX-501** or rimiducid.

(Emphasis added.)

87. The foregoing statements in ¶¶ 85-86 were false and misleading for the reasons set forth in ¶ 53. Defendants well knew, or were reckless in not knowing, that three pediatric patients had suffered encephalopathy with plausible causation by BPX-501, and one of those patients died.

88. On May 15, 2017, Bellicum filed a Form 8-K with the SEC, signed by Defendant Musso, along with a Management Changes press release, attached as an exhibit. In it, Fair states, “we prepare for the expected commercialization of BPX-501...”

89. The foregoing statements were false and misleading for the reasons set forth in ¶¶ 53, 87.

90. On June 23, 2017, at the 22nd congress of the European Hematology Association, an abstract from Bellicum’s poster presentation, co-written by COO Moseley again, contained the following statements:

Conclusion

These data suggest that Haplo-HSCT combined with infusion of BPX-501 T cells with a suicide gene may be a **safe and curative** option for children with hemoglobinopathies and ED who lack a matched donor. Infusion of gene modified T cells with an inducible suicide mechanism, combined with selective $\alpha\beta$ T-cell depletion, offers the potential to rapidly reverse GvHD and eliminate the need for the use of GvHD prophylaxis. Additionally, this approach results in rapid hematological and immune reconstitution for Haplo-HSCT recipients.

(Emphasis added.)

91. In the oral presentation, also co-written by Moseley, it stated:

Conclusion

Engraftment was brisk and T cell recovery normalized by 6 months. Overall incidence of severe aGVHD was low and the safety switch was successfully activated with rimiducid infusion. Cumulative incidence of NRM compares favorably to historic controls at the lead center, where a value of 2.4% for matched related donors (MR), 11.8% for matched unrelated donors (MUD) and 5% for $\alpha\beta$ T cell depletion haplo HSCT (Haplo $\alpha\beta$) without BPX-501 infusion was recorded (Bertaina, 2015 ASH). The cumulative incidence of relapse was 12.0% for BPX-501, 32.3% for MR, 22.2% for MUDs and 21.9% Haplo- $\alpha\beta$. Disease-free survival in the BPX-501 treated patients was 84.2% compared to 65.4% for MR, 66.1% for MUDs and 73.1% for Haplo- $\alpha\beta$. However, length of follow-up on the control cohorts differed from that of BPX-501 treated patients. These data suggest that BPX-501 T cells modified with the iCasp9 safety switch, infused after selective $\alpha\beta$ T-cell depletion, are **safe** and result in a rapid immune reconstitution and a potentially stronger GvL effect in children with high-risk leukemia who lack a matched donor.

(Emphasis added.)

92. The foregoing statements in ¶¶ 90-91 were false and misleading for the reasons set forth in ¶¶ 53, 87.

93. On May 8, 2017 Bellicum filed a Quarterly Report on form 10-Q with the SEC, announcing financial and operating results for the quarter ended March 31, 2017 (the “Q1 2017 10-Q”). The Q1 2017 10-Q contained signed certifications pursuant to SOX, like those described in ¶ 46, by Defendants Fair and Musso.

94. On June 28, 2017 Bellicum filed two S-3 Registration Statement forms (“S-3s”) with the SEC, signed by Fair and Musso.

95. The Q1 2017 10-Q and the S-3s contained the following Company statement:

We have discussions ongoing with the FDA regarding the regulatory path to approval in the U.S. and we expect to provide updates in the first half of 2017.

96. The foregoing statement was false and misleading for the reasons set forth in ¶ 53.

97. On August 8, 2017, Bellicum had their analyst earnings call for Second Quarter 2017 results. Within that call, Fair portrayed the regulatory path for BPX-501 as smooth:

Taken together, this affirms our belief that BPX-501 represents not just an important option for these patients, but also a significant commercial opportunity for us. Based on these findings, ***we continue to progress toward the market.***

* * *

Our objective for this study is to show superiority to the current standard of care in adult malignant patients who do not have a matched donor and to pursue registration in the U.S. and Europe in this population.

* * *

We're designing a registrational study in an ultra-orphan pediatric inherited blood disease where the need is most acute and the path to regulatory approval is most direct. **This should allow us to efficiently secure a pediatric approval in the U.S....**

* * *

And so, we've recast our plan in the U.S. to focus on a single ultra-orphan disease where the unmet need is the greatest, where **the regulatory path is clear and straightforward**, so that we can get an FDA approval. And we believe with the FDA approval, combined with the data set that we've generated across the U.S. and European programs, that U.S. treating physicians will have the information they need. So, it's a much more streamlined and efficient program, so that we can offer access to pediatric patients...

* * *

[W]e **have a supportive regulator in the U.S.** who buys into the benefit risk profile and is also cognizant of the issues that we will face in manufacturing and long-term safety follow-up that we were all vigilant about. But, we think they've offered a very realistic path to market for cell therapy and I think that's positive news for the whole community including us.

* * *

We don't have any pushback on the program that we have previously been devising in pediatrics in the U.S. from the FDA. We, as I indicated it, underwent a thorough strategic review of our entire portfolio, but particularly on BPX-501, recently concluded that and made the decision based on strategic priorities. As I mentioned, we felt like it wasn't the best use of our resources to do a large basket like trial in pediatrics in the U.S. that essentially replicated the BP-004 trial and the comparative MUD trial, which is the type of program that would have been required to get a comparable label. We see the largest opportunity in adult malignant setting and want to prioritize our resources there and on our future pipeline. But what we did see is the opportunity to provide access in the U.S. by a streamlined program to get an FDA approval and to leverage the totality of the data that we will have...

(Emphasis added.)

98. Moreover, on the August 8, 2017 call, Fair stated:

Third, as the cell therapy field evolves and advances, we remain convinced that our molecular switch platform to control the efficacy and **safety** of these therapies is increasingly relevant and the **best-in-class**."

* * *

"I believe we have an industry-leading platform that has the promise to do just this and we continue to invest to optimize it. During the quarter, we presented an exciting preclinical data on our novel dual-switch technology at AACR. The potential advantage of a dual switch is the ability to both activate cells to enhance

efficacy, and **eliminate them to manage toxicity** in a single product.”

* * *

“So, **that's the trial design that we're working with.** As far as providing more color about details about that endpoint sample size, we'll do that after we've had a chance to discuss the protocol with FDA. And so, when we come to you, we'll have a trial design that we're about to implement and that **we're comfortable that we will be registration or sending positive outcome.**”

(Emphasis added.)

99. On the August 8 earnings call Fair also claims that BPX-501's safety is “best-in-class” and on the verge of an FDA registration study, despite awareness of severe flaws in the clinical program and three cases of encephalopathy in pediatric patients treated with BPX-501.

100. The foregoing statements in ¶¶ 97-99 were false and misleading for the reasons set forth in ¶¶ 53, 87.

101. On August 8, 2017, Bellicum filed a Form 8-K with the SEC, signed by Defendant CFO Musso, along with an Operational Update and Financial Report for the Second Quarter ended June 30, 2017, attached as an exhibit. In it, Fair says: “We continue to be encouraged by the results from our ongoing BPX-501 pediatric studies and our progress toward a filing in Europe. We have adjusted our plans for U.S. registrational trials to enable an efficient path to seeking approvals for the greatest areas of unmet need.” The form also contained this statement from the Company:

Bellicum is finalizing plans for the design of registrational trials of BPX-501 in the U.S.

102. On August 8, 2017 Bellicum filed a Quarterly Report on form 10-Q with the SEC, announcing financial and operating results for the quarter ended June 30, 2017 (the “Q2 2017 10-Q”). The Q2 2017 10-Q contained signed certifications pursuant to SOX, like those described in ¶ 46, by Defendants Fair and Musso.

103. The Q2 2017 10-Q contained the following Bellicum statement:

We are finalizing plans for future U.S. clinical trials of BPX-501. We plan to pursue one or more clinical trials with the intent of filing for FDA approval.

104. The foregoing statements in ¶¶ 101-103 were false and misleading for the reasons set forth in ¶ 53.

105. The Q2 2017 10-Q and Q3 2017 10-Q spoke about neurotoxicity issues with CAR-T cell therapies but there is no disclosure of BPX-501 related neurotoxicity issues, despite widespread knowledge throughout the Company of the cases of encephalopathy plausibly related to BPX-501:

While high objective response rates have been reported in some hematological malignancies, serious and sometimes fatal toxicities have arisen in patients treated with CAR T cell therapies. These toxicities include instances in which the CAR T cells have caused high levels of cytokines due to over-activation, referred to as “cytokine release syndrome,” or CRS, neurologic toxicities and cases in which they have attacked healthy organs. In each case, these toxicities have sometimes resulted in death. In solid tumors, where the behavior of CAR T cells is particularly unpredictable and results have been inconsistent, enhanced CAR T cell approaches are being developed that raise even greater safety concerns.

106. The foregoing statements were false and misleading for the reasons set forth in ¶¶ 53, 87.

107. In September 2017, Bellicum presented at the Ladenburg Thalmann 2017 Healthcare Conference. On November 15, 2017, Bellicum also presented at the Jefferies 2017 London Healthcare Conference. The following slide was used in the Jefferies conference presentation, with a slight alteration in same slide used in the prior Ladenburg conference presentation, but no material difference:

BPX-501 Regulatory Strategy

Fast to market in pediatrics; adding to global standard of care in adults

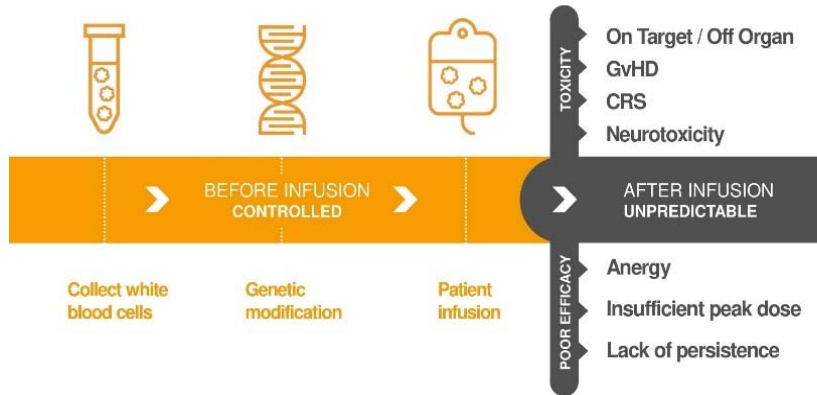
Pediatric	Adult
 <ul style="list-style-type: none">▪ BP-004 and observational MUD trial (C-004) are basis for filing▪ Regulatory bar set at non-inferiority on Event-Free Survival▪ Data readout expected 2H 2018▪ Filing expected 2019	 <ul style="list-style-type: none">▪ Conduct new trial in single ultra-orphan indication TBA▪ Trial to initiate in 2018
 <ul style="list-style-type: none">▪ Conduct new trial in adult AML▪ "Post Cy" regimen +/- BPX-501▪ Regulatory bar set at superiority▪ Trial to initiate in 2018	

108. In this slide on regulatory strategy for BPX-501, Bellicum is claiming they are “fast to market in pediatrics” and are on track for trials for adults, though Defendants knew the clinical program procedures regarding monitoring and managing of adverse events suffered severe flaws that could lead the FDA to place a hold on the clinical studies, particularly given three undisclosed cases of encephalopathy plausibly related to BPX-501 suffered during the trial.

109. Also, at these conferences, the Company presented the following slides:

Overview

Most cell therapies can only be controlled **before** infusion



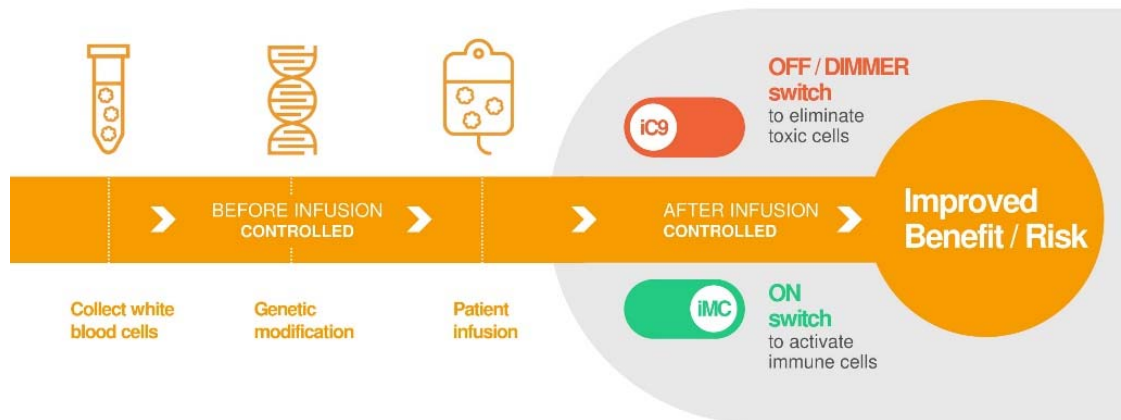
Bellicum

3

110. This slide states that “Most cell therapies can only be controlled before infusion,” and that after infusion, lack of control and unpredictability can lead to issues such as “neurotoxicity.”

Overview

Bellicum's molecular switches allow control **after** infusion



Bellicum

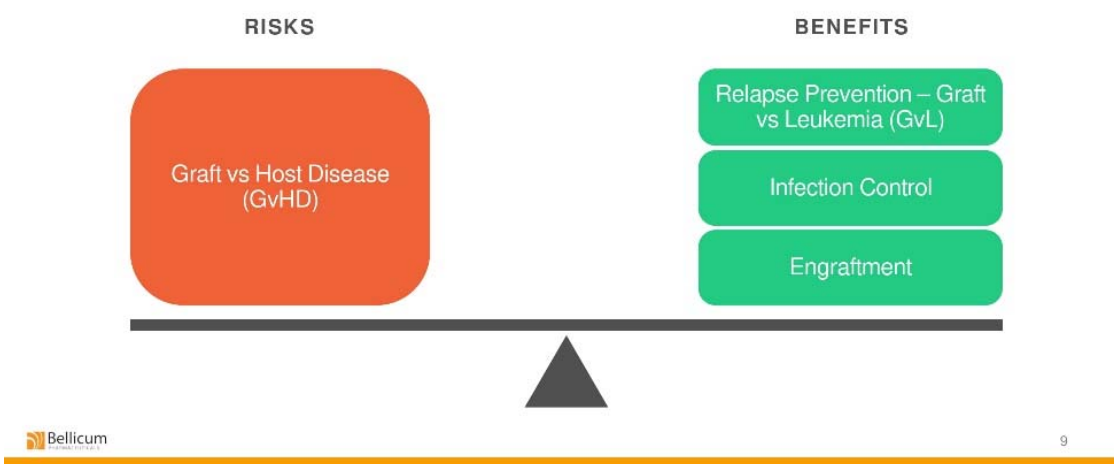
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111. The next slide claims what Bellicum does differently compared to “most cell therapies,” specifically that they can control what happens after the infusion of T-cells. The slide

has the claim that after there is infusion of the T-cells, when done by Bellicum using its drug regimen, the lack of control issue that other cell therapies experience, as detailed on the previous slide, goes away, and instead they can control what happens to eliminate toxic cells, and presumably, eliminate the adverse events detailed on the previous slide, such as neurotoxicity. This claim is made in these two presentations, both occurring after knowledge of encephalopathy in clinical trials is widespread within Bellicum.

T Cells in Allogeneic HSCT

T cells have benefits and risks in allogeneic HSCT, creating a difficult trade-off



112. This Bellicum slide presents the risks and benefits of “T-Cells in Allogeneic HSCT,” which is what BPX-501 does, and lists only “Graft vs Host Disease (GvHD),” while leaving out neurotoxicity/encephalopathy, despite these presentations occurring in September and November 2017, after awareness of the cases of encephalopathy.

113. The foregoing statements in ¶¶107-112 were false and misleading for the reasons set forth in ¶¶ 53, 87.

114. On November 7, 2017 Bellicum filed a Form 8-K with the SEC, signed by Defendant Musso, along with an Operational Update and Financial Report for the Third Quarter

ended September 30, 2017, attached as an exhibit. It had these relevant statements from Fair and from the Company, respectively:

Enrollment in our clinical program for BPX-501 remains on track and we progressed our plans for future trials in adult AML and a pediatric orphan blood disorder...

* * *

• Company Prepares for Additional BPX-501 Trials in U.S.

Planning is ongoing for two additional trials of BPX-501 to expand the eligible patient population and support potential U.S. registration. These trials are being developed in adult patients with acute myeloid leukemia (AML) and in a distinct orphan inherited blood disorder patient population.

115. On November 7, 2017 Bellicum filed a Quarterly Report on form 10-Q with the SEC, announcing financial and operating results for the quarter ended September 30, 2017 (the “Q3 2017 10-Q”). The Q3 2017 10-Q contained signed certifications pursuant to SOX, like those described in ¶ 46, by Defendants Fair and Musso.

116. The Q3 2017 10-Q had this statement from Bellicum:

We are working on plans and assessing feasibility for future U.S. clinical trials of BPX-501. We expect to pursue one or more clinical trials with the intent of an eventual filing for regulatory approval in the U.S.

117. The foregoing statements in ¶¶ 114-116 were false and misleading for the reasons set forth in ¶¶ 53, 87.

118. The positivity about the smooth continuation of the FDA approval process involving the BPX-501 clinical trial program, and eventual approvals for BPX-501, as discussed in ¶¶ 97-116, exists despite awareness of at least the UK 004 encephalopathy patient death by that point in 2017.

119. The statements referenced in ¶¶ 43-116 were materially false and/or misleading, because they misrepresented and/or failed to disclose that BPX-501 did not have a smooth

pathway to approval due to deleterious flaws in the BP-004 clinical trial protocols and procedures pertaining to the monitoring and managing of adverse events, that raised a risk that the FDA would place the BPX-501 clinical trials on a hold or may decline to approve the drug altogether. Indeed, three severe adverse events of encephalopathy occurred in three separate treatment centers, all deemed plausibly related to the drug, during the time that Bellicum had these deficient clinical trial procedures in place, none of which Defendants divulged during the Class Period. Defendants knew or recklessly disregarded these material adverse facts at all relevant times.

VI. THE TRUTH IS REVEALED

120. On January 30, 2018, post-market, Bellicum issued a press release entitled “Bellicum Pharmaceuticals Announces Clinical Hold on BPX-501 Clinical Trials in the United States,” which revealed the FDA placed a hold on BPX-501 clinical trials.

121. The press release stated:

Bellicum Pharmaceuticals, Inc. (NASDAQ:BLCM), a leader in developing novel, controllable cellular immunotherapies for cancers and orphan inherited blood disorders, today announced that the Company has received notice from the U.S. Food and Drug Administration (FDA) that U.S. studies of BPX-501 have ***been placed on a clinical hold following three cases of encephalopathy deemed as possibly related to BPX 501.***

Bellicum is awaiting formal communications from the FDA to determine the requirements for resuming studies, and will be working closely with the FDA to address their questions.

(Emphasis added.)

122. On this news, Bellicum’s share price fell \$2.12, or 25.85%, to close at \$6.08 on January 31, 2018.

123. The January 30, 2018 press release disclosed for the first time what Defendants had known all along – that BPX-501 contains a risk of neurological adverse events such as

encephalopathy that can lead to serious harm and even death, and revealed the actual cases that already transpired but were concealed. These cases also uncovered a severe flaw in the clinical procedures and safety protocols Bellicum had in place throughout the clinical trials to that date, which did not meet rigorous FDA standards.

124. As Bellicum explained in its March 13, 2018 10-Q, the Company could not conduct any clinical trials on BPX-501 during the duration of the hold. The FDA hold also raised a risk that foreign regulatory authorities would similarly impose clinical holds on ongoing trials of BPX-501, “which would significantly delay our development and could end our development of BPX-501.”

125. Then on the Q4 2017 earnings call held on March 13, 2018, Defendant Fair revealed that the FDA asked Bellicum to update its protocols and make clarifications for investigators about monitoring and managing neurotoxicity and all related adverse events in order to lift the hold and continue their trials.

126. Bellicum issued a press release on April 11, 2018 titled “Bellicum Announces Clinical Hold Lifted on U.S. Studies of BPX-501,” announcing that the FDA lifted the hold following amendments made to the BPX-501 study protocols to address the monitoring and management of neurotoxicity related adverse events, and to ensure investigators followed proper procedures for doing so.

127. As a result of Defendants’ wrongful acts and omissions, and the precipitous decline in the market value of the Company’s securities, Plaintiff and other Class members have suffered significant losses and damages.

VII. LOSS CAUSATION/MATERIALIZATION OF THE RISK

128. Defendants’ wrongful conduct, as alleged herein, directly and proximately caused the economic loss suffered by Plaintiff and the Class.

129. Throughout the Class Period, the price of Bellicum securities was artificially inflated and/or maintained at an artificially high level as a result of Defendants' materially false and misleading statements and omissions identified herein.

130. The price of the Company's securities significantly declined when the misrepresentations made to the market, and/or the information and risks alleged herein to have been concealed from the market, and/or the effects thereof, materialized and/or were revealed, causing investors' losses. As a result of Defendants' wrongful acts and omissions, and the precipitous decline in the market value of the Company's securities, Plaintiff and other Class members have suffered significant losses and damages.

VIII. NO SAFE HARBOR

131. The statutory safe harbor provided for forward-looking statements under certain circumstances does not apply to any of the allegedly false or misleading statements pleaded in this Complaint. The statements alleged to be false and misleading herein all relate to then-existing facts and conditions. In addition, to the extent certain of the statements alleged to be false may be characterized as forward looking, they were not identified as "forward-looking statements" when made, and/or there were no meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the purportedly forward-looking statements.

132. In the alternative, to the extent that the statutory safe harbor is determined to apply to any forward-looking statement pleaded herein, Defendants are liable for those forward-looking statements, because, at the time each of them was made, the speaker knew the forward-looking statements were materially false or misleading and/or the forward-looking statements were authorized and/or approved by an executive officer and/or director of Bellicum who knew that the forward-looking statements were false when made. In addition, the forward-looking

statements were contradicted by existing, undisclosed material facts that were required to be disclosed so that the forward-looking statements would not be misleading, and Defendants were aware of such facts. Finally, most of the purported “Safe Harbor” warnings were themselves misleading because they warned of “risks” that had already materialized or failed to provide any meaningful disclosures of the relevant risks.

IX. CLASS ACTION ALLEGATIONS

133. Plaintiff brings this action as a class action pursuant to Federal Rule of Civil Procedure 23(a) and (b)(3) on behalf of a Class, consisting of all those who purchased or otherwise acquired Bellicum securities during the Class Period (the “Class”); and were damaged upon the revelation of the alleged corrective disclosures. Excluded from the Class are Defendants herein, the officers and directors of the Company, at all relevant times, members of their immediate families and their legal representatives, heirs, successors or assigns and any entity in which Defendants have or had a controlling interest.

134. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, Bellicum securities were actively traded on the NASDAQ. While the exact number of Class members is unknown to Plaintiff at this time and can be ascertained only through appropriate discovery, Plaintiff believes that there are hundreds or thousands of members in the proposed Class. Record owners and other members of the Class may be identified from records maintained by Bellicum or its transfer agent and may be notified of the pendency of this action by mail, using the form of notice similar to that customarily used in securities class actions.

135. Plaintiff’s claims are typical of the claims of the members of the Class as all members of the Class are similarly affected by Defendants’ wrongful conduct in violation of federal law that is complained of herein.

136. Plaintiff will fairly and adequately protect the interests of the members of the Class and has retained counsel competent and experienced in class and securities litigation. Plaintiff has no interests antagonistic to or in conflict with those of the Class.

137. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class. Among the questions of law and fact common to the Class are:

- whether the federal securities laws were violated by Defendants' acts as alleged herein;
- whether statements made by Defendants to the investing public during the Class Period misrepresented material facts about the business, operations and management of Bellicum;
- whether the Individual Defendants caused Bellicum to issue false and misleading financial statements during the Class Period;
- whether Defendants acted knowingly or recklessly in issuing false and misleading financial statements;
- whether the prices of Bellicum securities during the Class Period were artificially inflated because of the Defendants' conduct complained of herein; and
- whether the members of the Class have sustained damages and, if so, what is the proper measure of damages.

138. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation make it impossible for members of the Class to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

139. Plaintiff will rely, in part, upon the presumption of reliance established by the fraud-on-the-market doctrine in that:

- Defendants made public misrepresentations or failed to disclose material facts during the Class Period;
- the omissions and misrepresentations were material;
- Bellicum securities are traded in an efficient market;
- the Company's shares were liquid and traded with moderate to heavy volume during the Class Period;
- the Company traded on the NASDAQ and was covered by multiple analysts;
- the misrepresentations and omissions alleged would tend to induce a reasonable investor to misjudge the value of the Company's securities; and
- Plaintiff and members of the Class purchased, acquired and/or sold Bellicum securities between the time the Defendants failed to disclose or misrepresented material facts and the time the true facts were disclosed, without knowledge of the omitted or misrepresented facts.

140. Based upon the foregoing, Plaintiff and the members of the Class are entitled to a presumption of reliance upon the integrity of the market.

141. Alternatively, Plaintiff and the members of the Class are entitled to the presumption of reliance established by the Supreme Court in *Affiliated Ute Citizens of the State of Utah v. United States*, 406 U.S. 128, 92 S. Ct. 2430 (1972), as Defendants omitted material information in their Class Period statements in violation of a duty to disclose such information, as detailed above.

X. COUNT ONE

(Violations of Section 10(b) of the Exchange Act and Rule 10b-5 Promulgated Thereunder Against All Defendants)

142. Plaintiff repeats and realleges each and every allegation contained above as if fully set forth herein.

143. This Count is asserted against Defendants and is based upon Section 10(b) of the Exchange Act, 15 U.S.C. § 78j(b), and Rule 10b-5 promulgated thereunder by the SEC.

144. During the Class Period, Defendants engaged in a plan, scheme, conspiracy and course of conduct, pursuant to which they knowingly or recklessly engaged in acts, transactions, practices and courses of business which operated as a fraud and deceit upon Plaintiff and the other members of the Class; made various untrue statements of material facts and omitted to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; and employed devices, schemes and artifices to defraud in connection with the purchase and sale of securities. Such scheme was intended to, and, throughout the Class Period, did: (i) deceive the investing public, including Plaintiff and other Class members, as alleged herein; (ii) artificially inflate and maintain the market price of Bellicum securities; and (iii) cause Plaintiff and other members of the Class to purchase or otherwise acquire Bellicum securities and options at artificially inflated prices. In furtherance of this unlawful scheme, plan and course of conduct, Defendants, and each of them, took the actions set forth herein.

145. Pursuant to the above plan, scheme, conspiracy and course of conduct, each of the Defendants participated directly or indirectly in the preparation and/or issuance of the quarterly and annual reports, SEC filings, press releases and other statements and documents described above, including statements made to securities analysts and the media that were designed to influence the market for Bellicum securities. Such reports, filings, releases and statements were materially false and misleading in that they failed to disclose material adverse information and misrepresented the truth about Bellicum's finances and business prospects.

146. By virtue of their positions at Bellicum , Defendants had actual knowledge of the materially false and misleading statements and material omissions alleged herein and intended thereby to deceive Plaintiff and the other members of the Class, or, in the alternative, Defendants acted with reckless disregard for the truth in that they failed or refused to ascertain and disclose such facts as would reveal the materially false and misleading nature of the statements made, although such facts were readily available to Defendants. Said acts and omissions of Defendants were committed willfully or with reckless disregard for the truth. In addition, each Defendant knew or recklessly disregarded that material facts were being misrepresented or omitted as described above.

147. Information showing that Defendants acted knowingly or with reckless disregard for the truth is peculiarly within Defendants' knowledge and control. As the senior managers and/or directors of Bellicum, the Individual Defendants had knowledge of the details of Bellicum's internal affairs.

148. The Individual Defendants are liable both directly and indirectly for the wrongs complained of herein. Because of their positions of control and authority, the Individual Defendants were able to and did, directly or indirectly, control the content of the statements of Bellicum. As officers and/or directors of a publicly-held company, the Individual Defendants had a duty to disseminate timely, accurate, and truthful information with respect to Bellicum's businesses, operations, future financial condition and future prospects. As a result of the dissemination of the aforementioned false and misleading reports, releases and public statements, the market price of Bellicum securities was artificially inflated throughout the Class Period. In ignorance of the adverse facts concerning Bellicum's business and financial condition which were concealed by Defendants, Plaintiff and the other members of the Class purchased or

otherwise acquired Bellicum securities at artificially inflated prices and relied upon the price of the securities, the integrity of the market for the securities and/or upon statements disseminated by Defendants, and were damaged thereby.

149. During the Class Period, Bellicum securities were traded on an active and efficient market. Plaintiff and the other members of the Class, relying on the materially false and misleading statements described herein, which the Defendants made, issued or caused to be disseminated, or relying upon the integrity of the market, purchased or otherwise acquired shares of Bellicum securities at prices artificially inflated by Defendants' wrongful conduct. Had Plaintiff and the other members of the Class known the truth, they would not have purchased or otherwise acquired said securities, or would not have purchased or otherwise acquired them at the inflated prices that were paid. At the time of the purchases and/or acquisitions by Plaintiff and the Class, the true value of Bellicum securities was substantially lower than the prices paid by Plaintiff and the other members of the Class. The market price of Bellicum securities declined sharply upon public disclosure of the facts alleged herein to the injury of Plaintiff and Class members.

150. By reason of the conduct alleged herein, Defendants knowingly or recklessly, directly or indirectly, have violated Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder.

151. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff and the other members of the Class suffered damages in connection with their respective purchases, acquisitions and sales of the Company's securities during the Class Period, upon the disclosure that the Company had been disseminating misrepresented financial statements to the investing public.

XI. COUNT TWO

**(Violations of Section 20(a) of the Exchange Act
Against the Individual Defendants)**

152. Plaintiff repeats and realleges each and every allegation contained in the foregoing paragraphs as if fully set forth herein.

153. During the Class Period, the Individual Defendants participated in the operation and management of Bellicum, and conducted and participated, directly and indirectly, in the conduct of Bellicum's business affairs. Because of their senior positions, they knew the adverse non-public information about Bellicum's misstatement of income and expenses and false financial statements.

154. As officers and/or directors of a publicly owned company, the Individual Defendants had a duty to disseminate accurate and truthful information with respect to Bellicum's financial condition and results of operations, and to correct promptly any public statements issued by Bellicum which had become materially false or misleading.

155. Because of their positions of control and authority as senior officers, the Individual Defendants were able to, and did, control the contents of the various reports, press releases and public filings which Bellicum disseminated in the marketplace during the Class Period concerning Bellicum's results of operations. Throughout the Class Period, the Individual Defendants exercised their power and authority to cause Bellicum to engage in the wrongful acts complained of herein. The Individual Defendants, therefore, were "controlling persons" of Bellicum within the meaning of Section 20(a) of the Exchange Act. In this capacity, they participated in the unlawful conduct alleged which artificially inflated the market price of Bellicum securities.

156. Each of the Individual Defendants, therefore, acted as a controlling person of Bellicum. By reason of their senior management positions and/or being directors of Bellicum, each of the Individual Defendants had the power to direct the actions of, and exercised the same to cause, Bellicum to engage in the unlawful acts and conduct complained of herein. Each of the Individual Defendants exercised control over the general operations of Bellicum and possessed the power to control the specific activities which comprise the primary violations about which Plaintiff and the other members of the Class complain.

157. By reason of the above conduct, the Individual Defendants are liable pursuant to Section 20(a) of the Exchange Act for the violations committed by Bellicum.

XII. PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment against Defendants as follows:

- A. Determining that the instant action may be maintained as a class action under Rule 23 of the Federal Rules of Civil Procedure, and certifying Plaintiff as the Class representative;
- B. Requiring Defendants to pay damages sustained by Plaintiff and the Class by reason of the acts and transactions alleged herein;
- C. Awarding Plaintiff and the other members of the Class prejudgment and post-judgment interest, as well as their reasonable attorneys' fees, expert fees and other costs; and
- D. Awarding such other and further relief as this Court may deem just and proper.

XIII. DEMAND FOR TRIAL BY JURY

Plaintiff hereby demands a trial by jury.

Dated: May 15, 2019

Respectfully submitted,

POMERANTZ LLP

/s/Tamar A. Weinrib

Jeremy A. Lieberman

Tamar A. Weinrib (admitted *pro hac vice*)

Villi A. Shteyn (*pro hac vice* application
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